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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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James H Heller

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EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

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1611

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03/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,013	Applicant(s) HELLER ET AL.	
	Examiner MARCOS SZNAIDMAN	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-40 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 17-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12, 16 and 23-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2 pages/ 01/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's reply filed on January 30, 2008.

Election/Restrictions

Applicant's election of Group I (claims 1-40) and donezepil as the cholinesterase inhibitor, in the reply filed on January 30, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

Cancellation of claim 9 and 41-48, and amendment of claims 3-8 is acknowledged.

Claims 1-8 and 10-40 are currently pending and are the subject of this office action.

Claims 13-15, and are 17-22 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 30, 2008.

Claims 1-8, 10-12, 16 and 23-40 are presently under examination.

Priority

The present application is a 371 of PCT/US03/22746 filed on 07/22/2003, and claims priority to provisional application No. 60/397,123 filed on 07/22/2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 10-12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt (US 6,458,807) or Ieni et. al. (US 2006/0018839).

Claims 1-2 and 10-12 recite a method to improve language information processing and learning comprising: prescribing or administering to a human subject that has specific learning disability relative to normal individuals, a dose of donepezil (species elected), said dose effective to increase specific domains of language performance wherein subject does not have: Down's syndrome, schizophrenia, attention deficit hyperactivity disorder, Alzheimer's disease, Parkinson's disease, head injury, dementia, memory deficit, Wernicke-Korsakoff's disease, Tardive Dyskinesia, vascular dementia, or depression, wherein the individual is an adult (claim 10) or a child (claim 11).

For claims 1-2, and 10-12 Pratt teaches a method for: treating mild cognitive impairments (see abstract and column 2, line 15), treating and preventing cognitive impairments associated with neurologic and/or psychiatric conditions (see column 2, lines 20-25), treating and preventing cognitive impairments associated or caused by brain lesions or other inflammatory diseases (see column 2, lines 44-50), by

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administering the cholinesterase inhibitor donezepil (see column 1, line 43). It also teaches a method for enhancing cognitive functions by administering to a patient a therapeutically effective amount of at least one of the cholinesterase inhibitor compounds described herein. Although Pratt does not explicitly mention “a method to improve language information processing and learning”, the skilled in the art will recognize that language information processing and learning are cognitive functions, so it will be obvious to treat individuals with learning disabilities with a method that the prior art describes to improve cognitive functions in the same type of population. To further clarify this concept, applicant is referred to Ieni et. al. that teaches a method for treating and preventing cognitive impairments (e.g., language development) caused by or associated with strokes, by administering to a patient in need thereof at least one cholinesterase inhibitor (see page 3, beginning of paragraph [0026]). The above references describe these treatments for the general population (i.e. children and adults).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to treat subject with a specific learning disability (cognitive function) by administering donezepil by following the method described by Pratt or Ieni et. al. that teach the treatment of cognitive impairments (e.g. language development), thus resulting in the practice of claims 1-2 and 10-12, with a reasonable expectation of success.

Claims 3-8 recite the same limitations as claims 1 and 2, wherein the human subject has language impairment (claim 3), developmental aphasia (claim 4), dyslexia (claim 5), minimal brain dysfunction (claim 6), and brain injury (claim 7) or has perceptual handicaps (claim 8).

For claims 3-8, Pratt further teaches a method for treating individuals with: dyslexia (see column 1, line 32), cognitive impairments caused by traumatic brain injury (see column 1, lines 23-24), comprising administering the cholinesterase inhibitor donepezil (see column 1, line 43). Ieni et. al. further teaches a method for treating post-stroke aphasia in a patient in need thereof by administering at least one cholinesterase inhibitor (see page 3, paragraph [0026]). Neither Pratt nor Ieni et. al. explicitly mention : “language impairment” , “minimal brain dysfunction” or “perceptual handicaps”, but these are symptoms that are always present in the population being subjected with these treatments.

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to treat subject with a specific learning disability (cognitive function), that further has language impairment, developmental aphasia, dyslexia, minimal brain dysfunction, and brain injury or has perceptual handicaps, by administering donepezil by following the method described by Pratt or Ieni et. al. that teach the treatment of cognitive impairments (e.g. language development), thus resulting in the practice of claims 3-8, with a reasonable expectation of success.

Claim 16, teaches the same limitations as claim 12, wherein the dose of donepezil is 1 to 10 mg/day.

For claim 16, leni et. al. further teach that the cholinesterase inhibitors can be administered in doses of about 0.01 mg/day to 300 mg/day, preferably about 1 mg/day to about 100 mg/day, more preferably about 5 mg/day to about 10 mg/day (see paragraph [0110]).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to administer an individual in need thereof donepezil within the dose range described in claim 16 based on the teachings of leni et. al., thus resulting in the practice of claim 16 with a reasonable expectation of success.

Claims 23-40 recite the same limitations as claims 1 and 2, wherein the subject in need further receives: educational therapy (claim 23), educational treatments for specific learning disability (claim 24), educational treatments for reading disability (claim 25), etc.

Neither Pratt nor leni et. al. teach any of these methods. However a person skilled in the art will immediately recognize that these are treatments specifically designed for patients with cognitive disorders (e.g. language, learning, reading problems, etc.), so at the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to administer an individual in need thereof donepezil in conjunction with any of the treatments of claims 23-40, with the motivation

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of improving the results of the drug treatment, thus resulting in the practice of claims 23-40, with a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MLS

February 21, 2008

/Michael P Woodward/

Supervisory Patent Examiner, Art
Unit 1615